



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

FEB 12 2004

Mr. Frederick A. Stearns
Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Dear Mr. Stearns:

Clariant GmbH has requested that attachments 3 and 4 of its Time and Extent Application (TEA) for piroctone olamine be considered confidential (page 4). FDA agrees that these attachments should be considered confidential commercial information according to 5 U.S.C. 552(b)(4) and 21 CFR 20.61(b) and (c).

The following information is redacted:

- Attachment 3: synthesis scheme
- Attachment 4: block production scheme

Both sections of the TEA that we have agreed to redact will be removed from the submission prior to its being put on display at the Division of Dockets Management. If you have any questions or comments, please contact Dr. Matthew Holman of this division at 301-827-2222.

Sincerely,

A handwritten signature in black ink, which appears to read "Charles J. Ganley, M.D.", is written over the typed name.

Charles J. Ganley, M.D.

Director,

Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research